



Atty. Docket No. 1501-1119

Patents

#14
MJS
7/22/03
RECEIVED
JUL 14 2003
TECH CENTER 1600/2900

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Eva GRAHN HAKANSSON et al

Serial No. 09/623,562

Filed November 16, 2000

Examiner I. Marx

AGENT

DECLARATION UNDER 37 C.F.R. §1.132

Commissioner for Patents

Washington, D.C. 20231

Sir:

I, Mikael G Bergstrand, hereby declare as follows:

I am a European Patent Attorney and Head of the Chemistry Department at Albihns IP & Law Offices and represent the applicant of the above identified application. I am well familiar with the present case and I have written the original Swedish Application. I am also supervising Ms Annika Unge who is currently responsible for the case. I have read and understood the Official Action dated August 9, 2002 and references cited therein. I make this declaration in support of the present application, and to provide evidence that bacterial strain ATCC 55883 is unavailable.

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The Swedish company Essum was going to conduct comparative experiments for the applicants of the present application. The experiments were going to compare the bacterial strain of the present invention with bacterial strain ATCC 55883. In order to conduct the experiments, numerous attempts were made to obtain bacterial strain ATCC 55883.

The appropriate International Deposit Authority (American Type Culture Collection) and the owner/depositor of bacterial strain ATCC 55883 were contacted on numerous occasions in an effort to obtain the strain. However, the International Deposit Authority and the depositor are either unwilling or incapable of providing applicants bacterial strain ATCC 55883.

Attached to this declaration are a series of correspondences between American Type Culture Collection (ATCC), the owner/depositor of bacterial strain ATCC 55883, and Essum.

As one can see, a request was made to ATCC on October 23, 2002, for a sample of bacterial strain ATCC 55883. The ATCC denied the request for the bacterial strain on the same day. The ATCC indicated that the strain was restricted and "not available for public distribution". On October 31, 2002, Essum directly contacted the depositor of strain ATCC 55883 and asked that the restricted patent clause be removed.

On November 13, 2002, the depositor released the strain from its restricted patent clause. However, despite the release of the strain, applicants are still unable to obtain the strain. Indeed, Essum has made numerous requests for the strain to the ATCC and the depositor of the strain. As shown in the e-mail of January 28, 2003,

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the depositor has informed Essum that they can not provide the strain and suggest that Essum contact the ATCC. However, upon contacting the ATCC again, the ATCC informs Essum on February 6, 2003, that the strain is not an accessioned item and that ATCC will not be producing the inventory. Thus, as the ATCC and the depositor are either unwilling or incapable of providing bacterial strain ATCC 55883, applicant believe that the strain is unavailable to the public.

The undersigned petitioner declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.



Mikael G Bergstrand

Stockholm, Sweden, July 4, 2003

Place and Date

Nunnally, Tanya, 13:48 2002-11-05 +0100, Re: ATCC No. 55883

From: daniel.ronnqvist@essum.se [mailto:daniel.ronnqvist@essum.se]
Sent: Wednesday, October 23, 2002 9:05 AM
To: sales@atcc.org
Subject: Website Email

Hello!

I wonder over this bacterial strain of Lactobacillus plantarum which according to different references should be an ATCC-strain. I would need to order this strain, but according to your distributor in Sweden it is not possible. I simply wonder why? According to The Budapest Convention Rule 11.3(b) to order it should NOT be a problem.
I am truly happy for a quick reply.

Item Number: 55883

Daniel Ronnqvist
Essum AB
Glimmervägen 5E
Umeå, 90750 Sweden

Nunnally, Tanya, 14:19 2002-10-24 +0200, Re: ATCC No. 55883

To: "Nunnally, Tanya" <nunnally@atcc.org>
From: Daniel Rönnqvist <daniel.ronnqvist@essum.se>
Subject: Re: ATCC No. 55883
Cc:
Bcc:
Attached:

2
Hello Tanya!

Thank you for your quick and straight answer. I would be very grateful if you could contact the depositor of ATCC 55883 to hear if it would be possible for you to send it to us. Please contact me when you know.

Thank you very much!

Daniel

1
At 14:02 2002-10-23 -0400, you wrote:
Dear Mr. Rönnqvist,

The item you have mentioned, ATCC No. 55883, is listed in our records as a restricted patent. It is not yet available for public distribution. It is the depositor's responsibility to inform the ATCC of the issuance of the pertinent U.S. patent to ensure release of the deposited item. To my knowledge, we have not been informed by the depositor of the issuance of a pertinent U.S. patent.

Since you have provided the ATCC with the U.S. patent number, we will contact the depositor to verify the information and ask for permission to release the strain. Please note the ATCC is simply the depository and has no ownership of the material. Ownership is retained by the depositor, therefore, the ATCC does not automatically release items upon the issuance of the pertinent patent. If you are in urgent need of the item you may contact the depositor yourself to request release or authorization to receive the item. If you have any further questions please contact me. Thank you.

Tanya Nunnally
Patent Specialist
American Type Culture Collection
Phone: 703-365-2721
Fax: 703-365-2745
E-mail: nunnally@atcc.org

-----Original Message-----

From: daniel.ronnqvist@essum.se [mailto:daniel.ronnqvist@essum.se]
Sent: Wednesday, October 23, 2002 9:05 AM
To: sales@atcc.org

Printed for Daniel Rönnqvist <daniel.ronnqvist@essum.se>

In

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2
To: Daniel Rönnqvist <daniel.ronnqvist@essum.se>
Subject: Re: ATCC strain

I have authorised the release of these strains.

Dr. Gregor Reid PhD MBA
Professor, Microbiology & Immunology, and Surgery, UWO
Program Leader, Advanced Surgical Technologies
Director, Canadian Research and Development Centre for Probiotics,
Lawson Health Research Institute,
268 Grosvenor Street,
London,
Ontario N6A 4V2
Canada

Tel: 519-646-6100 x65256

Fax: 519-646-6110

gregor@uwo.ca

www.crdc-probiotics.ca

— Original Message —

From: Daniel Rönnqvist

To: gregor@uwo.ca

Sent: Thursday, October 31, 2002 10:04 AM

Subject: ATCC strain

Hello Mr Reid!

7
My name is Daniel Rönnqvist and I work in Sweden with lactic acid producing bacteria. In one of Your patents (US 5,645,830) You have used different strains of lactobacillus; ATCC 55883 among others. I have tried to order this strain from the American Type Culture Collection (ATCC) in the US, but they replied that they could not distribute this strain in public because it was listed as a restricted item. Though, I really would like to use it in experiments comparing different strains of lactobacillus. Therefore I kindly want to ask You for permission to order this strain (ATCC 55883) from ATCC.

Please just send a note to Tanya Nunnally (nunnally@atcc.org) if it would be ok for me to order ATCC 55883. I would really like to hear from You too no matter what Your answer will be, just to ensure that no misunderstanding will occur.

Thank You in advance!

Daniel

Daniel Rönnqvist
tel. +46 90198140
fax. +46 90198144

ESSUM AB
Glimmervägen 5E
S-907 40 Umeå
Sweden

<http://www.essum.se>
info@essum.se

In

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At 11:20 2002-11-04 -0500, you wrote:
I have authorised the release of these strains.

Dr. Gregor Reid PhD MBA
Professor, Microbiology & Immunology, and Surgery, UWO
Program Leader, Advanced Surgical Technologies
Director, Canadian Research and Development Centre for Probiotics,
Lawson Health Research Institute,
268 Grosvenor Street,
London,
Ontario N6A 4V2
Canada

Tel: 519-646-6100 x65256
Fax: 519-646-6110
gregor@uwo.ca
www.crdc-probiotics.ca

In

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----- Original Message -----

From: Daniel Rönnqvist

To: Gregor Reid

Sent: Wednesday, November 13, 2002 7:59 AM

Subject: Re: ATCC strain

Hello Gregor!

This is Daniel from Sweden again. Unfortunately I have to trouble You again. Today I spoke to ATCC and they suggest You to send me Your authorization with Your signature by fax. I have attached a word-file wich is ready just to to sign. You can use that if You like or you can make one yourself, just remember to sign it.

Please fax it to: +46 90198144

Thank You very much for your help!

Best regards!

Daniel Rönnqvist

'03 02/07 06:11 FAX 0317461980

SCA

P → JALBINSTHLM

013

Gregor Reid, 09:24 2002-11-13 -0500, Re: ATCC strain

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Delivered-To: ne19251@localhost.obbit.se
From: "Gregor Reid" <gregor@uwo.ca>
To: Daniel Rönnqvist <daniel.ronnqvist@essum.se>
Subject: Re: ATCC strain
Date: Wed, 13 Nov 2002 09:24:06 -0500
X-Mailer: Microsoft Outlook Express 5.50.4133.2400

Done

11/13/02 10:18 FAX 518 471 0415

DR. G. REID

001



Grosvenor Cam
268 Grosvenor Street, Room H
London, Ontario N6A 4
Telephone 519-646-6
Facsimile 519-646-6
lriadm@lri.sjhc.london.on
www.lhri.onhcaith

FAX TO 469 019 8146

13 Nov., 2002

ATCC,
USA.

To whom it may concern,

Concerning a specific release of ATCC 55883, *Lactobacillus plantarum*

As a follow up to my authorization of release of a strain, I hereby repeat this approval in writing.

At this moment I authorize the release of the strain ATCC 55883, *Lactobacillus plantarum* to Daniel Ronnqvist at Essum AB, Umeå, Sweden. Daniel Ronnqvist is free to order this strain from ATCC and it can be released from it's restricted patent clause.

Yours sincerely,

Dr. Gregor Reid

skidact till 666 14/11.02

11/02/2003

12:52

PHNS STOCKHOLM AB → YOUNG & THOMSON

NR. 974

011

'03 02/07 08:11 FAX 0317481980

SCA

D → JALBINSTHLM

014

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In

----- Original Message -----

From: Daniel Rönnqvist

To: Gregor Reid

Sent: Tuesday, December 17, 2002 10:32 AM

Subject: ATCC strain

Hello Dr. Reid

This is Daniel from Essum AB, Sweden, writing.

We have encountered new problems ordering Your strain 55883 from ATCC. I don't really know what kind of problems, but they won't send it to us. Now I wonder if You by any chance have got any sample that we could get directly from You? Of course we will pay for all shipping costs.

Thank You!

Best regards!

Daniel Rönnqvist

Gregor Reid, 10:43 2002-12-20 -0500, Re: ATCC strain

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Delivered-To: ne19251@localhost.obbil.se
From: "Gregor Reid" <gregor@uwo.ca>
To: Daniel Rönqvist <daniel.ronnqvist@essum.se>
Subject: Re: ATCC strain
Date: Fri, 20 Dec 2002 10:43:00 -0500
X-Mailer: Microsoft Outlook Express 5.50.4807.1700

I'll ask my tech to do this in the new year. Not sure why ATCC can't do it as we authorised it.

Dr. Gregor Reid PhD MBA
Professor, Microbiology & Immunology, and Surgery, UWO
Program Leader, Advanced Surgical Technologies
Director, Canadian Research and Development Centre for Probiotics,
Lawson Health Research Institute,
268 Grosvenor Street,
London,
Ontario N6A 4V2
Canada

Bente Norlie, 08:35 2003-01-24 +0100, SV: ATCC bestilling av 55883

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2
Delivered-To: ne19251@localhost.obb.it.se
Reply-To: <bente.norlie@lgcpromochem.com>
From: "Bente Norlie" <bente.norlie@lgcpromochem.com>
To: 'Daniel Rönnqvist' <daniel.ronnqvist@essum.se>
Subject: SV: ATCC bestilling av 55883
Date: Fri, 24 Jan 2003 08:35:32 +0100
X-Mailer: Microsoft Outlook CWS, Build 9.0.2416 (9.0.2910.0)
Importance: Normal

Her er svaret som jeg har fått fra ATCC på onsdag. Skal holde deg oppdatert videre.

55883

(from ATCC)

When I checked this item, on January 10, it showed

a small amount in inventory with, apparently, no problems. It looks like now

they are unable to find inventory for this item in our facility, thus now

requesting additional vials from the depositor. There is no definitive time

frame for when the depositor may or will deposit additional material.

Therefore, I would ask that the customer check again with us in 5-6 months.

Sorry for the confusion, I was also confused when I looked at this item

recently since I had seen it available a very short time ago.

Vasia

MVH

Bente Norlie

LGC Promochem AB

P.O. Box 1737

SE-501 17 Borås

Tel. 033 165707

Fax. 033 165310

Please check our website www.lgcpromochem.com/atcc for product / price information and for online ordering

1
-----Ursprungligt meddelande-----

Från: Daniel Rönnqvist [mailto:daniel.ronnqvist@essum.se]

Skickat: den 17 januari 2003 10:08

Till: bente.norlie@lgcpromochem.com

Ämne: Re: ATCC bestilling av 55883

Hej Bente!

Vi har bestemt oss for att omedelbart beställa stammen ATCC 55883 via dig. Det skulle vara jättebra om du kunde mejla tilbake når du vet ungefär når vi får stammen.

✓ To: dlam@uwo.ca
Subject: Re: 55883 from ATCC

Hello!

Its not a problem for us if its not freezed-dried. I would be glad if You could send it as soon as possible. Thank You!

Daniel

Daniel Rönnqvist
tel. +46 90198140
fax. +46 90198144

ESSUM AB
Glimmervägen 5E
S-907 40 Umeå
Sweden

<http://www.essum.se>
info@essum.se

3 At 15:24 2003-01-17 -0800, you wrote:

I shall know by next Tuesday if I have a culture to send you. It won't be freezed-dried though. Hope it 's ok.

Dominique
.....

2 Daniel Rönnqvist wrote:

> Hello Dominique!
>
> That would be very kind of You. Please contact me by e-mail, as soon
> as possible, if You will / won't be able to provide me the strain.
>
> Thank You for your help!
>
> Kindest regards
> Daniel Rönnqvist
>

> -----
> Daniel RönnqvistESSUM AB<http://www.essum.se>
> daniel.ronnqvist@essum.seGlimmervägen 5Einfo@essum.se
> tel. +46 90198140S-907 40 Umeå
> fax. +46 90198144Sweden
>

1 > At 16:50 2003-01-15 -0800, you wrote:

>
>> Hello:
>>
>> I don't have a working stock of this strain. Will
>> try to obtain one for you . Please provide you
>> mailing address & phone number. Thank you
>>
>> Dominique Lam, M Sc

'03 02/07 08:12 FAX 0317481980

SCA

P → JALBINSTHLM

017

Dominique Lam, 11:35 2003-01-28 -0800, Re: 55883 from ATCC

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Delivered-To: ne19251@localhost.obbit.se

Date: Tue, 28 Jan 2003 11:35:57 -0800

From: Dominique Lam <dlam@uwo.ca>

Reply-To: dlam@uwo.ca

Organization: University of Western Ontario, London, Ontario, Canada

X-Mailer: Mozilla 4.76 [en] (Win98; U)

X-Accept-Language: en

To: daniel.ronnqvist@essum.se

Subject: Re: 55883 from ATCC

Hello Daniel:

I ran into some technical difficulty. In order not to hold you back, perhaps you should order this strain from ATCC. I am sorry about this.

Regards,
Dominique

11/02/2003

12:52

ALBIHNS STOCKHOLM AB → YOUNG & THOMSON

'03 02/07 08:12 FAX 0317481980

SCA

P → JALBINSTEHL

NR.974

D16

020

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Samuelsson Ann

From: Daniel Rönqvist [daniel.ronqvist@essum.se]

Sent: den 6 februari 2003 10:32

To: ann.samuelsson@sca.com

Subject: Denna gång...

... skickar jag även med "filen" (texten från maillet jag fick av LGC och ATCC :)

/Daniel

Hei Daniel,

Viderebefordrer et svar fra ATCC angående 55883, venter også på et skriftlig statement fra ATCC som jeg skal sende så snart jeg har det:

I apologize for all of the problems that we seem to be having with LGC and Restricted and Released Patents. We are working on trying to determine what the core problem is and then initiating corrective action.

Currently there is no distribution inventory for this item and we have contacted the depositor to see if they will provide us with more material. Because this is not an ATCC accessioned item, ATCC will not be producing the inventory.

Thank you.

Kristina M. Peterman

Regulatory Compliance & Patent Depository Manager

American Type Culture Collection

10801 University Boulevard

Manassas, VA 20110

Phone: 703-365-2700 x 309

Fax: 703-365-2745

e-mail: peterman@atcc.org

MVH

Bente Norlie

LGC Promochem AB

P.O. Box 1737

SE-501 17 Borås

Tlf. 033 165707

Fax. 033 165310

2003-02-06